510(k) SUMMARY

Single Use Preloaded Sphincterotome V

APR 1 1 2013

August 15, 2012

1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Sheri L. Musgnung
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
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  PO Box 610
  Center Valley, PA 18034-0610, USA
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  Email: sheri.musgnung@olympus.com

- Manufacturer: Aomori Olympus Co., Ltd.
  248-1 Okkonoki 2-chome Kuroishi-shi,
  Aomori, Japan 036-0367
  Establishment Registration No.: 9614641

2 Device Identification

- Device Trade Name: Single Use Preloaded Sphincterotome V
- Common Name: Sphincterotome
- Regulation Number: 21 CFR 876.4300
- Regulation Name: Endoscopic electrosurgical unit and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: KNS

3 Predicate Device Information

Manufacturer	Device Name	510(k) Number
Olympus Medical Systems Corp.	KD 6G1-9Q Wire Guided Papillotomy Knife	K950166
Terumo Corporation	Single Use Guidewire	K091417

4 Device Description

The subject sphincterotome consists of sphincterotome and preloaded guidewire. It is used in combination with endoscope and electrosurgical unit for papillotomy. The subject sphincterotome is composed of handle section and insertion tube. The preloaded guidewire is used for insertion and exchange of endotherapy accessories including the subject sphincterotome.

5 Indications for Use

These instruments (sphincterotomes and guidewires) have been designed to be used with an Olympus endoscope for papillotomy using high-frequency current. The preloaded guidewire is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

6 Comparison of Technological Characteristics

Compared to the predicate papillotomy knife, the subject sphincterotome has precurved distal end, coating on the cutting wire, three-lumen tube, and preloaded guidewire.

7 Substantial Equivalence Discussion

The indications for use of the subject sphincterotome is the combination of that of the predicate papillotomy knife and guidewire. The subject sphincterotome and predicate papillotomy knife are both used for endoscopic papillotomy with electrosurgical unit, and the guidewire is for guiding and exchanging endoscopic accessories including the subject sphincterotome.

Both of the subject sphincterotome and predicate papillotomy knife consist of handle section and insertion tube.

The major differences are as follows:

- The subject sphincterotome is guidewire-preloaded.
- The distal end of subject device is precurved.
- Coating is applied on the cutting wire.
- C-hook is provided in the handle section of the subject sphincterotome.

The preloaded guidewire is identical to the predicate except sterilization process, however, both the subject and predicate guidewire is sterilized by ETO.

These modifications do not raise any problems on the safety or effectiveness of the subject device.

8 Summary of Non-clinical Testing

The following biocompatibility tests were performed:

A. Cytotoxicity Test
B. Maximization Sensitization Test

C. Intracutaneous Irritation Test
D. Systemic Toxicity Test

Performance testing was conducted to demonstrate the initial performance of the subject device and confirmed that the subject device works as intended.

Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-2 and IEC 60601-2-18. In addition, verification was conducted to evaluate the mechanical and functional performance.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following standards have been applied to the Single Use Preloaded Sphincterotome V:

- IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
- IEC 60601-1-1: 2000
- IEC 60601-1-2: 2001, Amendment 1: 2004
- IEC 60601-2-2: 2006
- IEC 60601-2-18: 1996, Amendment 1: 2000
- ISO 10993-1: 2009
- ISO 10993-5: 2009
- ISO 10993-10: 2010
- ISO 10993-11: 2006
- ISO 11135-1: 2003
- ISO 14971: 2007
- ASTM F1980-07: 2007

9 Conclusion

When compared to the predicate device, the Single Use Preloaded Sphincterotome V does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2013

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Sheri Musgnung
Associate Manager, Regulatory Affairs
Olympus America Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K122505
Trade/Device Name: Single Use Preloaded Sphincterotome V
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: February 21, 2013
Received: February 25, 2013

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122505

Device Name: **Single Use Preloaded Sphincterotome V**

Indications For Use:

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Prescription Use___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122505